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Conflict and Balance Between Intellectual Property Protection of Pharmaceuticals and Public Health

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Abstract: In December 2019, the emergence of unexplained pneumonia (later named COVID-19) caught people all over the world off guard. Until now, the epidemic situation is still not optimistic, and global health is seriously threatened. Prevention and control measures for COVID-19, accurately all infectious diseases, people are no longer strange. There are three ways, that is, to control the source of infection (isolation), cut off the transmission path (wearing masks), and protect the susceptible population (vaccines and specific drugs).[1] Among them, the last link - screening and developing new drugs and vaccines is the focus of the current efforts of medical institutions, pharmaceutical companies, and scientific research institutions. In January 2020, the news that Chinese researchers at the Wuhan Institute of Virology filed for a patent on the use of Remdesivir, an investigational drug from the US company Gilead, caused widespread controversy, because patent protection would limit people's access to vaccines and drugs.[2] This also raises the question of how to balance the conflict between intellectual property protection for new pharmaceutical products and public health in the face of a global pandemic. This article mainly discusses three aspects, the fact of high cost, increasing complexities, and high rewarding of new pharmaceuticals, the status of strong protection in the pharmaceutical industry, and the negative public health impact of this strong protection. Although WTO members and some countries have responded accordingly to the consequences, the effect has been limited. This article will use this three-aspect analysis to in turn provide some information to increase the availability of vaccines and medicines for COVID-19 and other diseases.

Keywords: Patent; Intellectual Property Protection; Pharmaceuticals; Availability of Vaccines And Medicines; Public Health; Covid-19

1. The characteristics of pharmaceutical innovation: high cost, high difficulty, and high return

'The cost of this pill is one cent, but the first pill cost one hundred million dollars.' This is a popular phrase in the pharmaceutical industry. It also reflects the status of new drug research and development (R&D) - high costs. The cost here is broadly defined and includes the money, human and material resources, time, technical difficulty, and risk.[3]

Overall, pharmaceutical R&D is a high-investment, high-difficulty, and high-reward process. Its investment and difficulty are reflected in the long R&D cycle and high technical requirements. At the same time, it involves the close cooperation and collaboration of multiple disciplines, professionals, and talents. Take the R&D cycle as an example, a conventional approved drug needs to go through five important procedures from R&D to marketing: 'new drug discovery, pre-clinical research, clinical phase, marketing application and approval for marketing and post-marketing testing', and there are several branches under each procedure, resulting in extremely high investment of time, economic and technical costs. For instance, the clinical phase is divided into 3 or 4 steps with a long time span, of which the phase III trial phase is the most task-focused and important part, and the trial cycle is often calculated in years. In general, it often takes over ten years for an approved drug to go from R&D to marketing.[4] The cost and difficulty can be imagined, which are almost incomparable to

those in other industries.

Moreover, the risk of new drug R&D is considerably high. As mentioned above, there are many steps in the process and any mistake at any step can lead to failure, not to mention patent applications that are rejected at the final stage of approval. These 'halved' applications mean that the efforts made by many organizations and personnel have been wasted. The number of failures far exceeds the number of best-selling drugs.[5] The ability to bear risks reflects an enterprise's economic strength, which is why ordinary enterprises dare not dabble in new drug R&D.

Given that new drug development is so costly, risky, and difficult, should it be protected and generate high returns? The affirmative answer is understandable. Without a large enough benefit, normal people would have no incentive to do something strenuous. After all, not everyone can live their lives on spiritual support and tangible monetary gains are essential. Thus, protection is necessary. However, too much is too little, and excessive protection can have some detrimental effects. The following sections discuss in more detail the various types of protection afforded to pharmaceutical products, and the conflict and balance between the protection and public health.

2. Strong protection in the pharmaceutical industry: patents, trademarks, and other methods

Admittedly, life and health are priceless, and as medicine is so closely linked to human health, it seems that no protection can be too strong to be given to medicines. This notion has been implemented in many aspects of national and regional laws. It is fair to say that the protection currently afforded to medicines is adequate and is showing an increasing trend.[6] This article mainly analyses several means of protection: patents, trademarks, and other methods.

The first is patent protection. Compared with other industries, the pharmaceutical industry relies heavily on patent systems.[7] Patent, which is a kind of intellectual property right, is stipulated in various laws, including the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement of the World Trade Organization (WTO), the European Patent Convention (EPC), and the domestic laws in different countries. Although these laws are not identical, the purpose of the legislation is basically the same - to promote innovation by granting the patentee a legal monopoly.[8] Monopoly right during the limited period is the main way for pharmaceutical companies to make substantial profits. Therefore, it can be said that patent protection is related to the lifeblood of pharmaceutical industries.

At the level of being granted a patent, the threshold for granting a patent is lower for pharmaceuticals, which is considered to be 'privileged'.[9] In general, the criterion of a patent is novelty, creativity, and utility.[10] As medicine has evolved, the study of human disease has gradually moved from the individual to the organ, to the cell, and even to the molecule. Individualised and precise treatments have become popular, so it has become common for treatments to be 'slightly different' (rather than significantly) from existing methods.[11] For instance, as the saying goes, 'Talking about efficacy without talking about dose is nonsense', and a change in dose can affect efficacy. For example, a drug called Finasteride was found to treat an enlarged prostate and was patented, while another company used the same product, but with a change in dosage to treat male pattern baldness, which was also successfully patented.[12] Similar examples are not uncommon where drugs are patented as 'new' drugs by changing the dosage, dosage form, route of administration, etc., while leaving the active ingredient unchanged. The patent system appears to be more receptive to minor inventions of low inventiveness and small novelty in the pharmaceutical field than in other fields. In other words, patent protection in the pharmaceutical field is easier.

Since a patent has been granted, the patentee enjoys a legal monopoly, but the monopoly needs to be bound, most intuitively in the form of a limited-term, which is generally 20 years.[13] Once a drug goes through patent expiration, pharmaceutical companies would experience a 'patent cliff' [14] - a precipitous drop in sales and profits from the patent due to the onslaught of generics. This may sound regrettable, however, according to some data, the 12 best-selling drugs in the US enjoy an average of 38 years of protection.[15] Another study found that nearly 80% of the top 100 drugs had extended patent protection through a new patent.[16]

Then, why does the actual patent term far exceed the statutory period? As seen above, pharmaceutical companies can use minor differences to apply for new patents. In addition, there are a variety of ways to extend the protection period, such

as data exclusivity (quasi-intellectual property)[17], patent linkage system, and the pharmaceutical patent term compensation system (both provided for in the Trans-Pacific Partnership Agreement),[18] reverse payment settlements[19], citizen petitions[20], etc. Some have argued that this is understandable because, firstly, it is not illegal - there is no law against it - and, secondly, due to the existence of the patent cliff and the long delays in the approval process itself, it is reasonable for pharmaceutical companies to extend the profitability period. However, this practice has been much criticised. There is a term called 'evergreening' to describe this phenomenon, which is derogatory.[21] It is used as a metaphor for a phenomenon whereby pharmaceutical companies use various methods (not illegal but unethical) to extend the patent term. This phenomenon is detrimental to less affluent countries, as well as to generic companies, for whom access to patented medicines becomes more difficult.

In addition to patents, there is another type of intellectual property that can be used to protect drugs, which is trademarks.[22] Protection of pharmaceuticals is not normally associated with trademarks, because pharmaceuticals focus on intrinsic properties, such as efficacy, whereas trademarks protect relatively superficial objects, such as shape and colour. However, Pfizer's Viagra is a perfect example of how closely a trademark can be linked to the protection of a pharmaceutical product. Pfizer has taken Viagra, an erectile dysfunction treatment containing sildenafil, and engraved its image as a 'little blue pill' in the public mind through various strategies, including trademarks. In this case, therefore, the specificity of Viagra's appearance will prevent generic companies from selling a drug that looks like Pfizer's original product. Further, Viagra is not the only case. Many Chinese people know a 'pagoda candy' - a medicine that resembled a pagoda in shape and tasted like sugar but was essentially an insect repellent. The yellow, pagoda-shaped 'candy' has been imprinted on people's brains.[23] It does not matter whether the medicine is patented or not, whether there are variations in the ingredients, or even which manufacturer produces it, as long as it is this colour and shape, almost everyone recognises its effects and efficacy. This is also a successful case of a trademark and a drug being tied together, effectively protecting the interests of the drug.

In summary, pharmaceuticals are more likely to be granted patents and when facing the patent cliff, the patent term can be extended directly or indirectly in various ways. In addition, even after the expiry of the patent term, pharmaceutical products can still be protected by trademarks and other ways. It can be argued that the protection afforded to medicines is quite adequate. However, there has been much criticism from a growing number of countries, particularly developing and least developed countries, that pharmaceutical protection is slightly excessive, and that this has undoubtedly been detrimental to the entry of cheaper generic medicines into the market, which has been detrimental to public health.[24]

3. Conflict and balance between private rights (patent rights) and public interests (human rights)

'He just wants to live, what did he do wrong?' This is an impressive line from the movie Dying to Survive.[25] Adapted from a true event, the film tells the conflict between legal but expensive patented drugs, cheap but illegal generic drugs, and poor and life-saving cancer patients. In the film, the patented Gleevec for leukemia is very expensive, at over 20,000 RMB a box, it is unaffordable for an ordinary family, while generic Gleevec is cheap, at only 200 RMB a box, and there is no burden to use. For leukemia patients, as long as they can survive, there is no point in protecting intellectual property rights.

However, for pharmaceutical companies, the R&D of Gleevec has cost manufacturers more than ten years and a huge amount of money. To recover the cost as much as possible within the limited period, high-priced drugs are inevitable. If generic drugs, that is, drugs that are unauthorized to implement others' patents, are abused and cannot be effectively supervised, they will greatly infringe the interests of pharmaceutical companies, discourage their enthusiasm, and cause them to lose their motivation to R&D new drugs, and even endanger their survival.[26] This is detrimental to public health and the public interest.

As can be seen, innovation, law, and public health are in a triangular relationship, with all three influencing each other.[27] If innovation and public health are placed at opposite ends of a seesaw, then the law is the balance point of the seesaw, where the law encourages innovation while potentially infringing on public health. Countries are aware of this problem and have developed laws and policies, such as the Doha Declaration on the TRIPS Agreement and Public Health

(Doha Declaration), which recognises the right of developing countries to maximise the flexibility of the TRIPS Agreement to use compulsory licenses in situations where countries are experiencing emergencies, such as Aids, tuberculosis, malaria and other infectious diseases, like the COVID-19 now afflicting the world.[28] The birth of the Doha Declaration, which politically and legally empowers developing countries to access medicines, is a major event in the international intellectual property landscape.[29]

However, has the Doha Declaration fulfilled its role of increasing access to medicines in poor countries? Unfortunately, the results have fallen far short of expectations.[30] The Doha Declaration is soft law, which may be less binding and less enforceable than hard law.[31] It is a disappointing fact that the compulsory licensing system has been applied only once in the nearly 20 years since the Doha Conference. In October 2007, Canada notified the WTO that it had licensed a pharmaceutical company, Apotex, to produce a generic version of an exported patented drug for export to Rwanda. However, despite the efforts of both countries and Apotex, it still took five years before it could be exported. In the aftermath, Apotex stated that it would not use the compulsory licensing mechanism again unless reforms were made, as the process was too complex and cumbersome.[32] In other words, neither the number of compulsory licenses nor the availability of medicines has changed substantially because of the Doha Declaration.

In addition, some countries have made measures to facilitate the entry of generic drugs into the market. For example, the Hatch-Waxman Act, a US law designed to streamline the generic drug approval process and retain incentives for innovation.[33] Then the Bolar exemption, which originated in the US and was later followed by several countries, deems the importation, manufacture, and use of a patented drug by others for testing without the consent of the patent owner, to obtain data and other information required by the drug regulatory authority, as not infringement.[34] These provisions provide a legal basis for generic drugs, and although they have some effect, their usefulness is limited in the face of unexpected events where there is a high demand for patented drugs.

Finally, in response to specific major public health events, WTO members can make proposals. For example, in the current case of COVID-19, two key proposals have emerged to address the shortage of COVID-19 vaccine production - the South African and Indian proposal for an intellectual property waiver, and the European Union (EU) proposal to clarify compulsory licensing. These two proposals are still being discussed by the WTO. It is argued that both compulsory licenses and intellectual property waivers, have their advantages and disadvantages and the conclusion after comparison is that the latter is a more effective solution to the current emergency.

In short, the protection of intellectual property rights of medicine has indeed conflicted with public health in practice, and the WTO has made a special response to this situation, namely the Doha Declaration, and individual countries have introduced corresponding assistance regimes. In addition, in the face of current major public health events, proposals have been put forward by South Africa, India, and the EU. However, in general, the accessibility and affordability of patented medicines in poor countries have not been effectively improved. The current situation of the epidemic is serious and the health of people around the world is at risk, so legal provisions such as the Doha Declaration need to be put in place and made more efficient.

Conclusion

Conflicts and disputes about the protection of intellectual property rights of medicines and public health have never stopped, and the outbreak of the COVID-19 has pushed this conflict to a climax. Due to the high difficulty and high cost of drug R&D, to encourage innovation and promote social progress, the protection of drugs is strong, mainly including patents, trademarks, and other methods. However, the increasing variety of ways to extend the term of patents has resulted in patentees gaining monopoly rights for too long, which, combined with other means of protection, has made medicines expensive, undermining their accessibility and affordability to the public, particularly in developing and least developed countries. Although laws and policies have been put in place to improve this poor situation, the results have been unsatisfactory.

Pharmaceutical intellectual property protection should be used as a means to promote social welfare rather than as the ultimate goal and should not be at the expense of public health. Especially in the context of the current serious epidemic, it is

urgent to address public health issues. To resolve the conflict between pharmaceutical protection and the right to public health, and to seek a balance between them, the existing legal effects are not sufficient. It is recommended that countries amend their national intellectual property laws, including by removing institutional, political, and procedural barriers and improving the enforcement and efficiency of relevant provisions such as the existing patent compulsory licensing system, which will be more conducive to the long-term development of the pharmaceutical industry and human health.

References

[1] Kouadio IK, Aljunid S, Kamigaki T, Hammad K, Oshitani H. Infectious diseases following natural disasters: prevention and control measures. Expert Rev Anti Infect Ther. 2012 Jan;10(1):95-104. doi: 10.1586/eri.11.155. PMID: 22149618.

[2] Enrico Bonadio and Andrea Baldini, 'COVID-19, Patents and the Never-Ending Tension between Proprietary Rights and the Protection of Public Health' (2020) 11 European Journal of Risk Regulation 390.

[3] Paul Steven and others, 'How to improve R&D productivity: the pharmaceutical industry's grand challenge' (March 2010) Nature Reviews. Drug Discovery. 9 (3): 203.

[4] 'The Drug Development Process'. U.S. Food and Drug Administration (FDA). 4 January 2018. Accessed 21 December 2021.

[5] Graham Dutfield, 'Healthcare Innovation and Patent Law's "Pharmaceutical Privilege": Is There a Pharmaceutical Privilege? And If so, Should We Remove It?' (2017) 12 Health Economics, Policy and Law 468.

[6] Olga Gurgula, 'Compulsory Licensing vs. the IP Waiver: What Is the Best Way to End the COVID-19 Pandemic?' (2021) Policy brief 104.

[7] Graham Dutfield and Uma Suthersanen, Global Intellectual Property Law (Second Edition, Global Intellectual Property Law 2020) 379.

[8] Petra Moser, 'Patents and Innovation: Evidence from Economic History' (2013) Journal of Economic Perspectives, 27 (1): 23.

[9] Graham Dutfield, 'Healthcare Innovation and Patent Law's "Pharmaceutical Privilege": Is There a Pharmaceutical Privilege? And If so, Should We Remove It?' (2017) 12 Health Economics, Policy and Law 467.

[10] Graham Dutfield and Uma Suthersanen, Global Intellectual Property Law (Second Edition, Global Intellectual Property Law 2020) 179.

[11] Graham Dutfield, 'Healthcare Innovation and Patent Law's "Pharmaceutical Privilege": Is There a Pharmaceutical Privilege? And If so, Should We Remove It?' (2017) 12 Health Economics, Policy and Law 469.

[12] Graham Dutfield, 'Healthcare Innovation and Patent Law's "Pharmaceutical Privilege": Is There a Pharmaceutical Privilege? And If so, Should We Remove It?' (2017) 12 Health Economics, Policy and Law 463.

[13] Article 33 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

[14] Competition, D. G. 'Pharmaceutical sector inquiry-preliminary report' (2008) DG Competition Staff Working Paper.

[15] Alaric DeArment, 'Report blames gaming of patent system for high drug prices' (2018-08-09) Med City News. <https://medcitynews.com/2018/08/report-blames- gaming-of-patent-system-for-high-drug-prices/ > Accessed 25 December 2021.

[16] Erik Komendant, 'Anti-Competitive Evergreening Delays Patient Access to More Affordable Generics and Biosimilars | Association for Accessible Medicines.<https://accessiblemeds.org/resources/blog/anti-competitive-evergreening-delays-patient-access-more-affordable-generics> Accessed 25 December 2021.

[17] Graham Dutfield and Uma Suthersanen, Global Intellectual Property Law (Second Edition, Global Intellectual Property Law 2020) 404.

[18] 'The TPP and Pharmaceutical Protections: Too Strong, Too Weak, or Just Right?' (2016-5-25)<https://www.cato.org/events/tpp-pharmaceutical-protections-too-strong- too-weak-or-just-right > Accessed 25 December 2021.

[19] 'Agreements Involving Biosimilars Must Be Reported to FTC and DOJ Under New Law'<https://www.cooley.com/news/insight/2018/2018-10-19-agreements-involving-biosimilars-must-be-reported-to-ftc-and-doj-under-new-law> Accessed 25 December 2021.
[20] Federal Register, 'Citizen Petitions and Petitions for Stay of Action Subject to the Federal Food, Drug, and Cosmetic Act' (2019-09-19) <https://www.federalregister.gov/documents/2019/09/19/2019-20312/citizen-petitions-and-petitions-for-stay-of-action-subject-to-the-federal-food-drug-and-cosmetic-act>Accessed 25 December 2021.
[21] T. Amin and A.S. Kesselheim, 'Secondary Patenting of Branded Pharmaceuticals: A Case Study of How Patents on Two HIV Drugs could be extended for Decades' (2012) 31(10) Health Affairs 2286–94.
[22] Graham Dutfield, 'Not Just Patents and Data Exclusivity: The Role of Trademarks in Integrated IP Strategy–Where Lies the Public Interest?' Intellectual Property Law and Access to Medicines. Routledge (2021) 431.
[23] Zhang, HB, Liu, CS, & Zheng, Q, 'Development and application of anthelminthic drugs in China' Acta tropica 200 (2019): 105 181.
[24] Samira Guennif, 'Is compulsory licensing bad for public health? Some critical comments on drug accessibility in developing countries.' Applied health economics and health policy 15.5 (2017) 557.
[25] Hang J, 'Dying to Survive': Reflection on Realistic Themes and Its Artistic Presentation (2nd International Conference on Art Studies: Science, Experience, Education, Atlantis Press 2018) 797.
[26] Frederic M Scherer, 'Pharmaceutical innovation' Handbook of the Economics of Innovation 1 (2010) 539.
[27] Graham Dutfield, 'Healthcare Innovation and Patent Law's "Pharmaceutical Privilege": Is There a Pharmaceutical Privilege? And If so, Should We Remove It?' (2017) 12 Health Economics, Policy and Law 454.
[28] Paragraph 5 of the Doha Declaration on the TRIPS Agreement and Public Health.
[29] Tamar Gutner, International organizations in world politics (Los Angeles2017) 199.
[30] Frederick M Abbott, 'The WTO medicines decision: world pharmaceutical trade and the protection of public health' American Journal of International Law 99.2 (2005) 317.
[31] Sharifah Sekalala, Soft law and global health problems: Lessons from responses to HIV/AIDS, malaria and tuberculosis (Cambridge University Press 2017) 505.
[32] Graham Dutfield and Uma Suthersanen, Global Intellectual Property Law (Second Edition, Global Intellectual Property Law 2020) 410.
[33] Gerald J Mossinghoff, 'Overview of the Hatch-Waxman Act and its impact on the drug development process' Food & Drug LJ 54 (1999): 187.
[34] 'The principle behind the Bolar exemption is that generic companies should be in a position to take the necessary preparatory measures in order to be able to enter the market without delay once patent protection expires' in Decision T 0223/11 dated 22 May 2012 of the Board of Appeal 3.3.02 of the European Patent Office, reasons 2, fifth paragraph.